



EC DECLARATION OF CONFORMITY

MANUFACTURER:

DIESSSE DIAGNOSTICA SENESE SPA
VIA DELLE ROSE 10
53035 MONTERIGGIONI (SI),
ITALY



EUROPEAN REPRESENTATIVE:

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PRODUCT:
CODE:

**CHORUS COXSACKIE B CONTROL SERUM
85903**

CLASSIFICATION:

IVD NOT IN ANNEX II OR SELF-TESTING IVD

CONFORMITY ASSESSMENT ROUTE:

ANNEX APPLIED N° III

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PREVISIONS OF THE COUNCIL DIRECTIVE 98/79EC FOR IN VITRO DIAGNOSTIC MEDICAL DEVICE. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

NOTIFIED BODY:

NOT NECESSARY

(EC) CERTIFICATE:

N.A.

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6

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THE PRESENT EC DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE AND EXCLUSIVE RESPONSIBILITY OF THE MANUFACTURER.

SIGNATURE:

CHIARA MUZZI
QUALITY & REGULATORY MANAGER

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ISSUED: MONTERIGGIONI, 06/04/2021

MAGDALENA STOCZKO
REGULATORY SUPERVISOR